DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

September 12, 2014

Vioptix Inc.
c/o Mr. Greg Holland
Regulatory Specialist
3722 Ave. Sausalito
Irvine, CA 92606 US

Re: K133983
Trade/Device Name: Intra. Ox Handheld Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter, Tissue Saturation
Regulatory Class: Class II
Product Code: MUD
Dated: August 5, 2014
Received: August 7, 2014

Dear Mr. Greg Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

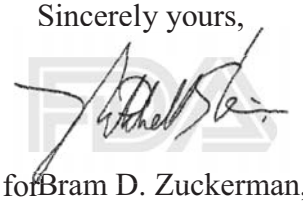
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21
CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part
803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



forBram D. Zuckerman,
M.D. Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

**Indications for Use Statement**

**Indications for Use**

**510(k) Number (if known): _____**

**Device Name:** Intra.Ox™ Handheld Tissue Oximeter

Indications for Use:

The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation ($StO_2$) in a volume of tissue.

The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**510(k) Summary**

47224 Mission Falls Court · Fremont, CA 94539
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| | |
|---|---|
| Submitter's Name | ViOptix, Inc. |
| Address | 47224 Mission Falls Ct., Fremont, CA 94539 |
| Contact at ViOptix | Mark Lonsinger |
| Telephone | 510-360-7506 |
| Fax | 510-226-5864 |
| Email | info@vioptix.com |

Date the Summary was prepared: December 20, 2013

Information regarding Application Correspondent:

| | |
|---|---|
| Official Correspondent | Greg Holland |
| Address | 3722 Ave. Sausalito<br>Irvine, CA 92606 |
| Telephone | 949-262-0411 |
| Email | greg@regulatoryspecialists.com |

**Information regarding the device classification:**

| | |
|---|---|
| Trade Name: | Intra.Ox™ Handheld Tissue Oximeter |
| Common Name: | Tissue Oximeter |
| Classification regulation: | 21 CFR 870.2700 |
| Classification regulation name: | Oximeter |
| Product code: | MUD |
| Device Class: | II |

**Information regarding the legally marketed device to which we are claiming equivalence [807.92(a)(3)]:**

| | |
|---|---|
| 510(k) Reference # | K042657 |
| Device Name | ODISsey Tissue Oximeter |
| 510(k) Holder | ViOptix |

**Description of the Device:**

The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a sterile, cordless, battery-powered device that non-invasively estimates the percent oxygen saturation ($StO_2$) in a volume of tissue. The device uses spatially-resolved optical

measurements at four wavelengths. The device performs measurements on the patient by direct physical contact to the patient's tissue and displays the $StO_2$ estimate on the built-in screen. The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a single-use disposable constructed from biocompatible materials that can tolerate bodily fluids and other liquids such as disinfectants and marking materials.

**Indications for Use:**
The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation ($StO_2$) in a volume of tissue.

The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

**Intended Use:**
The Intra.Ox™ Handheld Tissue Oximeter has the same intended use as the predicate, the T.Ox.

**Technological Characteristics:**

| Parameter | Subject Device: Intra.Ox™ | Predicate Device: T.Ox (formerly known as ODISsey) |
|---|---|---|
| 510K number | This submission | K042657 |
| Manufacturer | ViOptix, Inc. | ViOptix, Inc. |
| **Intended Use** | | |
| Indications for Use | The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation ($StO_2$) in a volume of tissue.<br><br>The Intra.Ox ™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations. | The ViOptix ODISsey Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation ($StO_2$) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.<br><br>The ODISsey Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation. |
| Measured Parameters | Tissue oxygen saturation (% $StO_2$) | Tissue oxygen saturation (% $StO_2$) and trend graph |
| Operating Principle | Spectrophotometric oximetry | Spectrophotometric oximetry |
| Energy Delivered | Near-infrared light<br>Source: LED chips<br>Wavelengths: 760, 810, 850, 900 nm | Near-infrared light<br>Source: laser diodes<br>Wavelengths: 690, 830 nm |
| Single Patient Use? | Yes, integrated sensor and control unit is single patient use disposable. | Sensor is single patient use disposable. Control unit is reusable. |
| Power Source | Battery powered<br>Battery type: 4 Lithium AA<br>Battery voltage: 6 V total | Mains powered with battery backup<br>Battery type: 3-cell Lithium ion |

| Parameter | Subject Device: Intra.Ox™ | Predicate Device: T.Ox (formerly known as ODISsey) |
|---|---|---|
| Measurement Range | 1-99% $StO_2$ | 1-99% $StO_2$ |

**Performance Testing**

**Bench Tests**

The Intra.Ox™ devices were found to measure absorption coefficients with a high degree of correlation to actual absorption coefficients in liquid phantoms prepared with Intralipid and swine whole blood. The correlation coefficient was greater than 0.9 for each of the four wavelengths used in the devices.

The Intra.Ox™ devices were shown to agree well with the predicate device in $StO_2$% measurements. Over three full-scale (complete oxygenation to complete deoxygenation) blood desaturations, three different Intra.Ox™ devices as compared to two T.Ox devices showed combined limits of agreement of +8.49 and -7.50 percentage points. The acceptance criterion required the limits of agreement to be less than ±10 percentage points. Therefore, the Intra.Ox™ is demonstrated to be substantially equivalent to the T.Ox in estimating $StO_2$%.

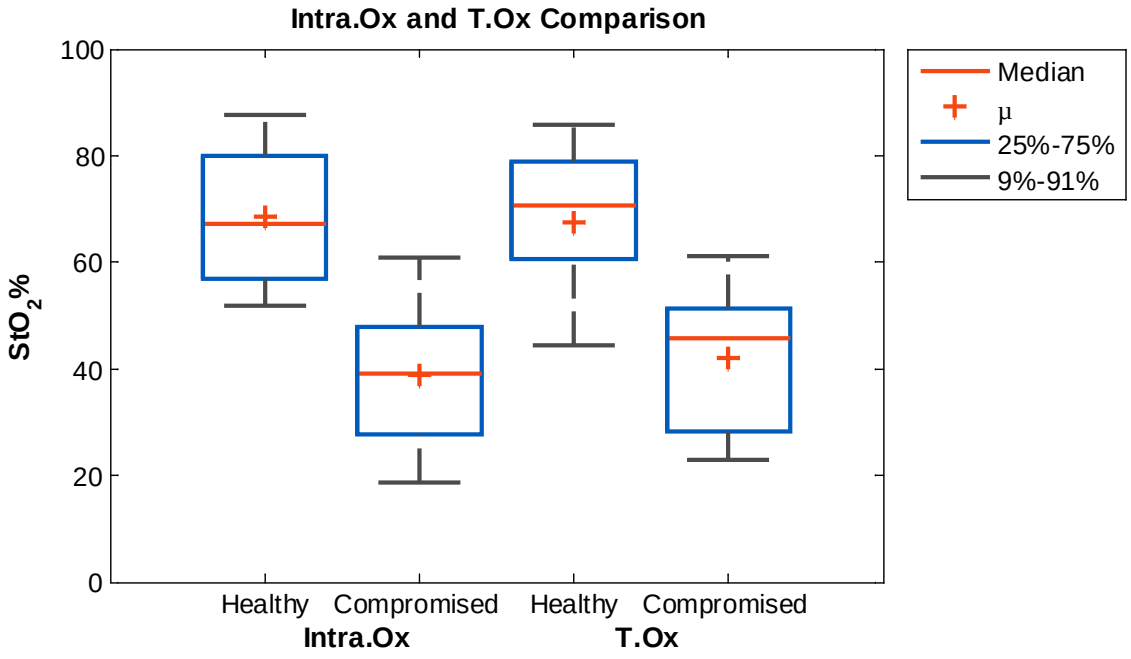
**Clinical Study**

Performance was determined by measuring tissue oxygen saturation ($StO_2$) with both devices during transient ischemic events on healthy human volunteers that temporarily mimics compromised tissue. Data from 11 subjects, who were near-evenly distributed over age, gender, and skin color as determined by the Fitzpatrick skin type, were analyzed.

There was excellent agreement in shape of the ischemic events between the Intra.Ox™ and T.Ox devices. A direct comparison with paired data showed good agreement considering the physiological variances inherent between measurement sites.

The mean baseline value of 68% and mean desaturation dynamic range of 30 percentage points agrees well with literature-reported values of skin and muscle transient ischemia.

Importantly, the Intra.Ox™ and T.Ox measure similar ranges of $StO_2$ values for both healthy and compromised tissue, thus validating substantial equivalence.




**Conclusion**

The Intra.Ox™ Handheld Tissue Oximeter has the predicate device identified above, has the same intended use as the predicate, has similar technology that does not raise new types of questions of safety or effectiveness, and performance data shows that this device provides reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.